

Message Text

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71

ORIGIN HEW-06

INFO OCT-01 AF-08 EUR-12 EA-09 ISO-00 OES-06 EB-07 COME-00

MED-03 /052 R

DRAFTED BY DHEW/FDA JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP WJWALSH, III

DHEW/OIH: MACODDING

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P 212218Z JUL 76

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY REYKJAVIK PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY PRETORIA PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, BE, IC, IT,SF, SP,SW

SUBJ: FDA ADVISORY - (RECALL NO.) T-125-6, SHARPLY
POINTED END OF URETERAL CATHETERS

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT: URETERAL CATHETERS, WHISTLE TIP, X-RAY OPAQUE,
GRADUATED, STERILE DISPOSABLE PLASTIC. SIZES 3-8 FRENCH,
COLOR CODED FOR USE ON RIGHT OR LEFT SIDES, CATHETERS ARE
OF PVC COMPOSITION, BARIUM LOADED TO BE X-RAY OPAQUE. PRO-
DUCT NO. 1801.

PRODUCT IDENTIFICATION: EACH CATHETER IS LABELED WITH THE
FOLLOWING INFORMATION, PRODUCTION DATE (YEAR END DAY OF
YEAR) EX. 6016 INDICATES 1976 AND THE 16 DAY OF THE YEAR),
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ACMI USA, AND THE FRENCH SIZE EX. NO. 5 FR. EACH CATHETER

IS SEALED BETWEEN TWO SHEETS GLASSINE PAPER, AND THEN IT IS SEALED BETWEEN SHEETS OF CLEAR POLYETHYLENE/MYLAR AND TYVEK PAPER, LABELED AS FOLLOWS "ACMI URETERAL CATHETER, AMERICAN LATEX CORPORATION, SUBSIDIARY OF ACMI, SULLIVAN, INDIANA 47882 XXX STERILE XXX STERILITY OF CONTENTS NOT GUARANTEED IF A PACKAGE IS OPENED OR DAMAGED. DO NOT AUTOCLAVE PACKAGE. CONTENTS NOT TO BE REUSED. CAUTION: FEDERAL LAW RES-

TRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN."

TWENTY FOUR (24) UNITS (12 EACH OF THE 2 COLOR CODES) ARE PACKAGED IN A CARBOARD CARTON LABELED IN PART, "ACMI STERILE URETERAL CATHETERS XXX AMERICAN LATEX CORPORATION, SUBSIDIARY OF ACMI, SULLIVAN, INDIANA XXX CAUTION: FEDERAL LAW RESTRICTS XXX CONTENTS NOT TO BE REUSED XXX 12 PAIRS". THE PRODUCT NUMBER, CATHETER SIZE AND PRODUCT NAME ARE PRINTED ON THE GLASSINE PAPER AND CAN BE READ THROUGH THE POLYETHYLENE/MYLAR FILM, EXAMPLE - "1081 4 FR WHISTLE TIP G".

LOT NUMBERS: 2081, 2083, 2091, 2094, 2099, 2102, 2105, 2111, 2113, 2123, 2127, 2129, 2134, 2142, 2143. THE LOTS ARE ALSO DESIGNATED AS STERILE RUN NUMBERS. THE STERILE RUN NUMBER (LOT NO.) IS IMPRINTED ON THE PRINTED SIDE OF THE TYVEK PAPER.

MANUFACTURER/RECALLING FIRM: AMERICAN LATEX CORPORATION
SUBSIDIARY OF ACMI
609 CHANEY STREET
SULLIVAN, INDIANA 47882

CONTACT FOR FIRM: MR. JAMES F. VANCE, GENERAL MANAGER
AMERICAN LATEX CORPORATION, TELEPHONE NO. 812-268-638L.

2. REASON FOR RECALL ADVISORY: FROM 2/13/76 TO 6/15/76
THE FIRM HAD RECEIVED 6 COMPLAINTS REGARDING SHARP TIPS ON THE DISTAL END OF THE CATHETER. PRIOR TO 2/13/76 THE FIRM HAD NOT RECEIVED ANY COMPLAINTS REGARDING THIS DEVICE. IN FOLLOWING UP A NUMBER OF COMPLAINTS BY PHYSICIANS
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CONCERNING THE SHARPNESS OF THE TIPS OF THE CATHETER AND A COMPLAINT BY A PHYSICIAN THAT A PATIENT'S BLADDER HAD BEEN PERFORATED BY SUCH A CATHETER, PRODUCTION OF THE PRODUCT WAS STOPPED ON 5/21/76. PRIOR TO THIS DATE THE CATHETERS WERE PRODUCED BY EXTRUDING THE TUBING, CUTTING THE TUBING INTO THE REQUIRED LENGTHS, AND ONE END CLOSED OFF IN A GLASS MOLD TO GIVE A ROUNDED TIP. DRAINAGE HOLES ARE THEN PUNCHED AT SPECIFIC LOCATIONS. THE TIP WAS

THEN SLICED OFF LEAVING AT LEAST 50 PERCENT OF THE ROUNDED TIP ON THE CATHETER END AND THE TIP WAS FINISHED BY HAND USING 400 GRIT SILICON PAPER. FOLLOWING FDA'S INSPECTION OF THE FIRM ON 6/25/76 IT WAS NOTED THAT THE FIRM'S MANAGEMENT HAD MET WITH THEIR EMPLOYEES TO MAKE THEM AWARE OF THE REASONS FOR PRODUCT QUALITY CONTROL. THE FIRM NOW CUTS THE "WHISTLE TIPS" BY MACHINE INSTEAD OF BY HAND IN ORDER TO GET A MORE ACCURATE AND UNIFORM CUT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS DATED JUNE 30 TO JULY 1, 1976 REQUESTING RETURN OF THE 15 SUBJECT LOTS OF THE PRODUCT. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS REFERRED TO ABOVE. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL ADVISORY SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

CONSIGNEE NAME AND ADDRESS	CATHETER SIZE (FRENCH SIZE)	NO. OF DATE SHIPPED	LOT NO. UNITS (STERILE (INDIV- RUN NO.) IDUAL CATHET- ERS)
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WATSON, VICTOR	3 FR.	1/14/76	48 UNITS 2102
LTD. N. RYDE	5 FR.	12/19/75	48 " 2099
AUSTRALIA	5 FR.	12/19/75	96 " 2099
	5 FR.	12/19/75	48 " 2099
	5 FR.	1/14/76	96 " 2099

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FUETER & CO.	6 FR.	2/5/76	24 " 2105
BRUSSELS,	6 FR.	4/7/76	24 " 2129
BELGIUM	7 FR.	4/7/76	24 " 2129
	8 FR.	1/16/76	48 " 2105
	8 FR.	1/16/76	48 " 2103

INKAUPASTOFNUN	3 FR.	12/10/75	48 " 2094
REYKJAVIK, ICE-4	FR.	12/10/75	48 " 2094
LAND			

AUSTURBAKKI H.F.	3 FR.	12/10/75	24 " 2094
REYKJAVIK, ICE-			
LAND			

EMMANULE	4 FR.	12/15/75	48 " 2094
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MANICINI POL- 5 FR. 12/15/75 48 " 2099
ERMO, ITALY

PROTEA HOLD- 4 FR. 1/14/76 48 " 2102
INGS, LTD. 5 FR. 1/14/76 48 " 2099
NATAL PTY. LTD.
NATAL, SOUTH
AFRICA

PROTEA HOLD- 3 FR. 10/22/75 96 " 2081
INS LTD. JOH- 3 FR. 10/22/75 96 " 2081
ANNESBURG
SOUTH AFRICA

SURGICAL & 3 FR. 10/24/75 720 " 2081
MEDICAL SUP- 4 FR. 10/24/75 1200 " 2081
PLIES JOH- 4 FR. 12/10/75 1992 " 2094
ANNESBURG 4 FR. 1/14/76 168 " 2102
SOUTH AFRICA

PRIM S.A. 3 FR. 1/6/76 24 " 2094
MADRID, SPAIN 4 FR. 1/21/76 72 " 2102
5 FR. 4/22/76 24 " 2111

STILLE WERNER 5 FR. 2/18/76 24 " 2111
A.S. STOCK- 5 FR. 3/12/76 24 " 2111
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HOLM, SWEDEN ROBINSON

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL CARE, EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 21 JUL 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE180742
Document Source: CORE
Document Unique ID: 00
Drafter: CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760281-0500
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760735/aaaabekb.tel
Line Count: 202
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: hackerp0
Review Comment: n/a
Review Content Flags:
Review Date: 26 FEB 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <26 FEB 2004 by ThomasVJ>; APPROVED <07 JAN 2005 by hackerp0>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - (RECALL NO.) T-125-6, SHARPLY POINTED END OF URETERAL CATHETERS
TAGS: OGEN, ETRD, EIND, TBIO, AS, BE, IC, IT, SF, SP, SW, US, FDA, AMERICAN LATEX CORP
To: CANBERRA
MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006